UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,076	07/17/2003	Rudolf Gilmanshin	C0989.70054US00	1842

7590 05/30/2006

Helen C. Lockhart
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210

EXAMINER	
BERTAGNA, ANGELA MARIE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,076	GILMANSHIN, RUDOLF	
	Examiner	Art Unit	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,68,91 and 112-128* is/are pending in the application.

4a) Of the above claim(s) *35 and 112-124* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34,68,91 and 125-128* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2/04; 12/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-34, 68, 91 and 125-128, in the reply filed on March 6, 2006 is acknowledged. The traversal is on the ground(s) that search of all groups together would not pose a serious burden to the examiner. This is not found persuasive, because since a coextensive search cannot be performed for all groups, a burden does exist. As discussed previously, a search for the apparatus of Group II would be directed to the specific features of the apparatus and would not require additional search terms directed to the methods of using the apparatus (Group I) or a composition that can be used with the apparatus (Group III). Likewise, a search for the compositions of Group III would be directed to the specific compositions of nucleic acid tags and nucleic acid binding enzymes and would not require search terms directed to methods of using the compositions (Group I) or an apparatus in which the compositions could be used (Group II). In other words, each of Groups I, II, and III requires a different, non-overlapping search of the prior art. A simultaneous search for Groups I-III would pose a serious search burden to the examiner, and therefore, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 35 and 112-124 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 26, 2006.

Claim Objections

2. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 recites "The method of claim 1, further wherein the nucleic acid binding agent binds to the polymer non-specifically." Claim 1 recites this limitation in step (b) by stating, "allowing the nucleic acid binding agent to bind to the polymer non-specifically."

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 34, and 126-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "the system of claim 19". There is insufficient antecedent basis for this limitation in the claim, because claim 19 recites "the method of claim 1".

Claim 34 recites the limitation "the system of claim 1" in line 1. There is insufficient basis for this limitation in the claim, because claim 1 is drawn to a method.

Claim 34 is also indefinite, because it contains the trademark/trade name Gene Engine. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C.

112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a method for determining a hybridization pattern and, accordingly, the identification/description is indefinite.

Claims 126-128 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step of labeling the polymer. The preamble of claim 126 recites "a method for labeling a polymer", but the claim does not contain a step where a polymer is labeled.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-8, 10-11, 16-18, 24-25, 27-28, 30-31, 91, and 125-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Norton et al. (Bioorganic & Medicinal Chemistry, 1995; abstract cited in IDS).

The instant claims are drawn to a method of analyzing a nucleic acid using a conjugate comprising a specifically bound nucleic acid tag and a non-specifically bound nucleic acid-binding agent.

Regarding claims 1-6, 10-11, 91, and 125-128, Norton teaches a method of analyzing a polymer (see page 440 "Selective cleavage of supercoiled plasmid by the PNA-nuclease conjugates") wherein a peptide nucleic acid (PNA)-nuclease conjugate is annealed to DNA. The nucleic acid tag molecule (PNA) hybridizes specifically to the DNA (conjugates Ia and II specifically hybridize to inverted repeat sequences), and the nucleic acid binding agent (nuclease) associates non-specifically with the DNA substrate. In other words, the nuclease is capable of translocating along the DNA substrate. The cleavage pattern resulting from the hybridization reaction was then analyzed by gel electrophoresis.

Regarding claim 7, the PNAs of Norton are 16 or 20 residues in length (page 439, "Purification of PNAs").

Regarding claim 8, Norton teaches covalently coupling the PNA and nuclease (abstract, where the PNA is linked via a disulfide bond).

Regarding claims 16-17, Norton teaches that the cleaved polymer fragments are subjected to agarose gel electrophoresis and visualization via ethidium bromide staining (page 440, column 2). This comprises labeling the polymer with a backbone-specific label.

Regarding claim 18, Norton teaches the use of the nucleic acid binding agent (nuclease) that is not inherently a detectable moiety (pages 439-440 teach that the nuclease is not labeled or otherwise detectable).

Regarding claim 24, Norton teaches that the DNA substrate is not an in vitro amplified nucleic acid (pages 440 and 444 teach the use of plasmid DNA rather than an amplification product).

Regarding claim 25, Norton teaches that the nucleic acid tag molecue (PNA) is not an antisense nucleic acid (page 440 teaches that the PNA hybridizes to inverted repeats and do not teach use of the PNA tag as an antisense molecule).

Regarding claims 27-28 and 30, Norton teaches that the PNA tag is labeled with an agent capable of cleaving a nucleic acid (page 440 teaches that the PNA is conjugated or "labeled" with a functional nuclease).

Regarding claim 31, Norton teaches detection of the cleavage products using agarose electrophoresis (page 440, column 2). This method indirectly detects the presence of the binding agent (nuclease).

6. Claims 1, 3-9, 13-14, 16-17, 22, 24, 26-27, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Grigoriev et al. (PNAS, 1993; cited in IDS).

The instant claims are drawn to a method of analyzing a nucleic acid using a conjugate comprising a specifically bound nucleic acid tag and a non-specifically bound nucleic acid-binding agent.

Regarding claims 1 and 3-6, Grigoriev teaches hybridizing a psoralen-oligonucleotide conjugate to a target DNA sequence followed by detection using electrophoresis (see Methods section pages 3501-3502, column 1; see also page 3503, 2nd full paragraph). The nucleic acid tag molecule (the 15-mer DNA oligonucleotide) binds specifically to the target sequence (page 3503, 1st full paragraph), whereas the nucleic acid binding agent (psoralen) binds nonspecifically.

Regarding claim 7, the oligonucleotide tag molecule of Grigoriev is 15 residues in length (page 3502, lines 4-9).

Regarding claims 8-9, Grigoriev teaches that the psoralen and oligonucleotide tag molecule are covalently linked via a hexamethylene linker (page 3502, 1st paragraph).

Regarding claims 13-14 and 22, the psoralen molecule that serves as the nucleic binding agent in the method of Grigoriev is detectable using fluorescence spectroscopy. Since this molecule is covalently attached to the nucleic acid tag, the nucleic acid tag molecule is also "labeled with a detectable moiety".

Regarding claims 16-17, Grigoriev teaches that fragments of the substrate bound to the psoralen-oligonucleotide conjugate were analyzed by gel electrophoresis followed by ethidium bromide staining (page 3502, 2nd full paragraph). The ethidium bromide staining is a form of labeling the polymer with a backbone specific label.

Regarding claim 24, Grigoriev teaches that the polymer is a plasmid DNA rather than an amplification product (page 3502, 2nd full paragraph).

Regarding claim 26, Grigoriev teaches that the psoralen-oligonucleotide conjugate hybridizes specifically to promoter of the IL-2Ra gene rather than to the bacterial sequences of the plasmid DNA substrate (page 3502, column 2).

Regarding claims 27 and 30, the psoralen and oligonucleotide components of the conjugate taught by Grigoriev are covalently linked (page 3502, lines 4-9). Therefore, the nucleic acid tag molecule is "labeled with an agent", specifically the psoralen molecule. Psoralen is capable of modifying a nucleic acid, specifically by forming cross-links (see abstract).

Regarding claim 31, Grigoriev teaches detection of the hybridized products using gel electrophoresis (page 3502, 2nd full paragraph). This method indirectly detects the presence of the binding agent (psoralen).

7. Claims 1, 3-9, 16-18, 24, and 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Magda et al. (US Patent No. 5,798,491).

The instant claims are drawn to a method of analyzing a nucleic acid using a conjugate comprising a specifically bound nucleic acid tag and a non-specifically bound nucleic acid-binding agent.

Regarding claims 1 and 3-6, Magda teaches hybridizing a texaphyrin-oligonucleotide conjugate to a target DNA or RNA sequence followed by detection using electrophoresis (Example 1, column 10, line 60 – column 11, line 67; see also column 3, lines 18-42). The nucleic acid tag molecule (the oligonucleotide) binds specifically to the target sequence (column

9, line 67 – column 10, line 16), whereas the nucleic acid binding agent (texaphyrin) interacts with the target nonspecifically.

Regarding claim 7, the oligonucleotide tags taught by Magda are 20 residues in length (Figure 1, SEQ ID Nos: 1 & 2).

Regarding claims 8-9, Magda teaches that the texaphyrin and oligonucleotide tag molecule are covalently linked optionally via a linker (column 7, lines 38-51).

Regarding claims 16-17, Magda teaches that fragments of the radiolabeled substrate bound to the texaphyrin-oligonucleotide conjugate were analyzed by gel electrophoresis (column 38-67). The 32P used to label the substrate DNA is a backbone specific label.

Regarding claim 18, the texaphyrin nucleic acid binding agent taught by Magda is not itself a detectable moiety.

Regarding claim 24, Magda teaches that the polymer is a synthetic DNA rather than an amplification product (see Figure 1, SEQ ID Nos: 3 & 4; example 1, column 11, lines 38-41 teach that these are synthetic products).

Regarding claim 26, Magda teaches the use of texaphyrin-oligonucleotide conjugate that hybridize specifically to eukaryotic sequences (column 10, lines 43-48).

Regarding claims 27-30, the texaphyrin and oligonucleotide components of the conjugate taught by Magda are covalently linked (column 7, lines 38-51). Therefore, the nucleic acid tag molecule is "labeled with an agent", specifically texaphyrin. Texaphyrin is capable of modifying a nucleic acid, specifically via photocleavage and hydrolysis reactions (see abstract).

Regarding claim 31, Magda teaches detection of the hybridized products using gel electrophoresis (column 11, lines 63-67). This method indirectly detects the presence of the binding agent (texaphyrin).

8. Claims 1-11, 13-15, 18, 21-27, 30-32, 91, and 126-128 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Hyldig-Nielsen et al. (US Patent No. 6,280,946 B2; cited in IDS).

The instant claims are drawn to a method of analyzing a nucleic acid using a conjugate comprising a specifically bound nucleic acid tag and a non-specifically bound nucleic acid-binding agent.

Regarding claims 1-6, 10-11, 91, and 126-128, Hyldig-Nielsen teaches an in situ hybridization method wherein a peptide nucleic acid (PNA)-enzyme conjugate is annealed to DNA (see abstract and column 3, lines 8-12). Hyldig-Nielsen further teaches that the enzyme (nucleic acid binding agent) may be a DNA polymerase (column 7, lines 51-56). The nucleic acid tag molecule (PNA) hybridizes specifically to the DNA (column 9, lines 59-62), and the nucleic acid binding agent (DNA polymerase) associates non-specifically with the DNA substrate in addition to possessing translocation ability. The hybridization pattern was then detected (see for example, column 27, lines 14-26, where fluorescently labeled probes are detected).

Regarding claim 7, Hyldig-Nielsen teaches PNA sequences of 18 nucleotides (see abstract).

Regarding claims 8 and 9, Hyldig-Nielsen teaches covalently coupling the PNA and nucleic acid binding agent (polymerase) using a linker molecule (column 8, lines 10-16).

Regarding claims 13, 22, and 23, Hyldig-Nielsen teaches labeling of the nucleic acid tag molecule (PNA) with dextran conjugates, a branched nucleic acid detection system, a chromophore, a fluorophore, a spin label, a radioisotope, an enzyme, a hapten, an acridinium ester, or a chemiluminescent compound (column 7, lines 30-39). Hyldig-Nielsen also teaches detection of these labels using, for example, a microscope, photographic film, a luminometer, a laser scanning device (column 18, lines 28-30), or a CCD detection system (column 29, lines 19-20).

Regarding claim 14, Hyldig-Nielsen teaches that PNA may be conjugated to the alkaline phosphatase enzyme (column 7, lines 51-56) which itself serves as a label.

Regarding claim 15, Hyldig-Nielsen teaches that the use of multiple labels, for example, an enzymatic label (such as alkaline phosphatase, which also serves as a non-specific nucleic acid binding agent) combined with a fluorescent PNA-bound label (column 11, lines 42-49).

Regarding claim 18, Hyldig-Nielsen teaches the use of the nucleic acid binding agent (polymerase) that is not inherently a detectable moiety.

Regarding claims 21, 24, and 25, the method of Hyldig-Nielsen is a FISH method (abstract). The nucleic acid targets used in the Hyldig-Nielsen method are not amplified in vitro prior to hybridization, nor are the PNA probes antisense molecules.

Regarding claim 26, Hyldig-Nielsen teaches probes specific for eukaryotic sequences (see abstract).

Regarding claims 27 and 30, the enzyme and PNA components of the conjugate taught by Hyldig-Nielsen are covalently linked (column 8, lines 10-16). Therefore, the nucleic acid tag molecule is "labeled with an agent", specifically the enzyme. The alkaline phosphatase enzyme disclosed by Hyldig-Nielsen is capable of modifying a nucleic acid, specifically by removing the 5'-terminal phosphate.

Regarding claims 31 and 32, Hyldig-Nielsen teaches detection of the hybridization products using fluorescence detection of PNA-bound labels (see for example, column 11, lines 34-41). This method indirectly detects the presence of the binding agent (DNA polymerase). Hyldig-Nielsen also teach antibody-based detection (column 12, lines 40-50).

9. Claims 1-8, 10-12, 18, 24-28, 30-31, 91, and 125-128 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Fisher et al. (US Patent No. 6,362,328 B1).

The instant claims are drawn to a method of analyzing a nucleic acid using a conjugate comprising a specifically bound nucleic acid tag and a non-specifically bound nucleic acid-binding agent.

Regarding claims 1-6, 10-11, 91, and 125-128, Fisher teaches method for detecting nucleic acids (such as DNA or RNA) using an oligonucleotide-nuclease P1 conjugate (see abstract and column 4, lines 36-56). The nucleic acid tag molecule (DNA or RNA) hybridizes specifically to the nucleic acid target (column 6, lines 5-12), and the nucleic acid binding agent (P1 nuclease) associates non-specifically with the DNA substrate in addition to possessing translocation ability. The hybridization pattern was then detected (column 4, lines 53-64).

Regarding claim 7, Fisher teaches a nucleic acid tag sequence of 35 residues (column 6, lines 15-16).

Regarding claim 8, Fisher teaches covalently coupling the P1 nuclease and oligonucleotide tag (column 4, lines 37-39).

Regarding claim 12, Fisher teaches that the pH of the reaction is maintained above pH 7.0, thereby preventing P1 nuclease-catalyzed cleavage of the nucleic acid substrate (column 2, lines 48-54).

Regarding claim 18, Fisher teaches the use of the nucleic acid binding agent (P1 nuclease) that is not inherently a detectable moiety.

Regarding claims 24 and 25, the plasmid DNA target used in the Fisher method was not amplified in vitro prior to hybridization, nor were the oligonucleotide probes designed to function as antisense molecules (Example 11, column 8, lines 15-43).

Regarding claim 26, Fisher teaches probes specific for eukaryotic sequences (column 6, lines 5-12).

Regarding claims 27, 28, and 30, the P1 nuclease and oligonucleotide components of the conjugate taught by Fisher are covalently linked (column 4, lines 37-39). Therefore, the nucleic acid tag molecule is "labeled with an agent", specifically the P1 nuclease. Furthermore, although the pH of the reaction has been adjusted to prevent P1 nuclease from cleaving the nucleic acid substrate, the enzyme has not been otherwise modified (i.e. by mutation), and therefore, the enzyme is still inherently capable of cleaving (and thereby, modifying) a nucleic acid molecule.

Regarding claim 31, Fisher teaches detection of the hybridization products using chemiluminescent detection (column 4, lines 53-64). This method indirectly detects the presence of the binding agent (P1 nuclease).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 19, 20, 33, 34, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Norton et al. (Bioorganic & Medicinal Chemistry, 1995), Grigoriev et al. (PNAS, 1993), Magda et al. (US Patent No. 5,798,491), Hyldig-Nielsen et al. (US Patent No. 6,280,946 B2), or Fisher et al. (US Patent No. 6,362,328 B1) in view of Tegenfeldt et al. (WO 00/09757; cited in IDS).

The instant claims are drawn to the method of claim 1, further wherein, a single polymer linear analysis system is used to determine the hybridization pattern.

Norton, Grigoriev, Magda, Hyldig-Nielsen, and Fisher separately teach the method of claim 1, as discussed above.

None of these references teach detection using a linear polymer analysis system.

Tegenfeldt teaches a system for optically analyzing polymers (abstract).

Regarding claim 19, the system is a linear polymer analysis system (abstract).

Regarding claim 20, Tegenfeldt teaches that the system is useful for performing a sequencing application wherein a nucleic acid is labeled with a fluorescent or radioactive label and subsequently exposed to an interaction station where the fluorescent/radioactive signal is detected (see pages 7-8, in particular the 1st full paragraph of page 8; see also claim 1).

Regarding claim 33, the system is capable of analyzing single polymers (page 8).

Regarding claim 34, the system described by Tegenfeldt is the Gene Engine system (see paragraph 9 of the instant application's specification which states, "The Gene Engine system is described in published PCT Patent Applications WO 98/35012, WO 00/09757...").

Regarding claim 68, Tegenfeldt teaches a method (see page 9, lines 6-15) comprising:

(a) generating optical radiation of a known wavelength to produce a localized radiation spot

(b) passing a polymer through a microchannel

(c) irradiating the polymer at the localized spot

(d) sequentially detecting radiation resulting from interaction of the polymer with the optical radiation at the localized radiation spot

(e) analyzing the polymer based on the detected radiation.

Tegenfeldt teach the above method for the specific application of sequencing a nucleic acid molecule, but do not teach analysis of a polymer bound to a conjugate of a nucleic acid tag molecule and a nucleic acid binding agent.

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use the detection system of Tegenfeldt to analyze the hybridization pattern produced by the methods of any of Norton, Grigoriev, Magda, Hyldig-Nielsen, or Fisher. Tegenfelt

particularly pointed the advantages of the linear analysis system over the conventional detection methods employed by Norton, Grigoriev, Magda, Hyldig-Nielsen and Fisher, namely increased speed and simplicity of the assay (see page 7, lines 16-20 and page 11, lines 9-22). Although the focus of the Tegenfeldt disclosure is on improving available sequencing methods, these advantages would have also been highly applicable to the hybridization-based methods of Norton, Grigoriev, Magda, Hyldig-Nielsen and Fisher, where slow and laborious methods including gel electrophoresis, chemiluminescent detection and fluorescence visualization were utilized. Therefore, the ordinary practitioner of the hybridization method taught by any of Norton, Grigoriev, Magda, Hyldig-Nielsen, or Fisher, interested in obtaining a faster and simpler method of detection, would have been motivated to incorporate the linear analysis system taught by Tegenfeldt, thus resulting in the instantly claimed methods.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Angela Bertagna
Patent Examiner
Art Unit 1637

amb

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/24/06